

External Quality Assessment Scheme

## Glucose meters Round 1, 2023

### Specimens

Please find enclosed samples S001, S002 and/or S003, each 1 mL., according to your order. S001 is for all glucose meters except Contour, HemoCue and On Call Plus, S002 is for HemoCue meters and S003 for Contour meters. S001 and S003 are human based whole blood material, S002 is a bovine based haemolysate.

### Caution

Quality control specimens (S001 and S003) are derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Quality control sample S002 is bovine based, and do not carry biohazards for man, but it should be handled with same care as patient samples, i.e. as potential transmitters of serious diseases.

### Examinations

Glucose

### Storage and use

Store unopened vial in a refrigerator (+2...+8 °C). Allow sample to stand for at least 15 minutes at room temperature before use. It is important that the sample has reached the room temperature before analysing it. Mix the sample by turning the vial upside down about 10 times before use. Open the vial, turn it upside down and squeeze the vial to get a drop of the sample. Discard the first drop. Analyse as a patient sample. Sample can be stored at +2 ... +8 °C. Sample is stable until the round is closed.

NOTE! StatStrip Xpress 2-users: identify the sample as a control i.e., analyze in QC-mode.

### Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator. Please insert expire date and lot-number of used strips to LabScala.

S001:



S002:



S003:



2023-03-13

### INSTRUCTIONS

Product no. 2570, 2580, 2590  
LQ729123011-13 /NL/UK

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi)

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The results should be reported no later than  
**April 12, 2023.**

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### Inquiries

EQA Coordinator  
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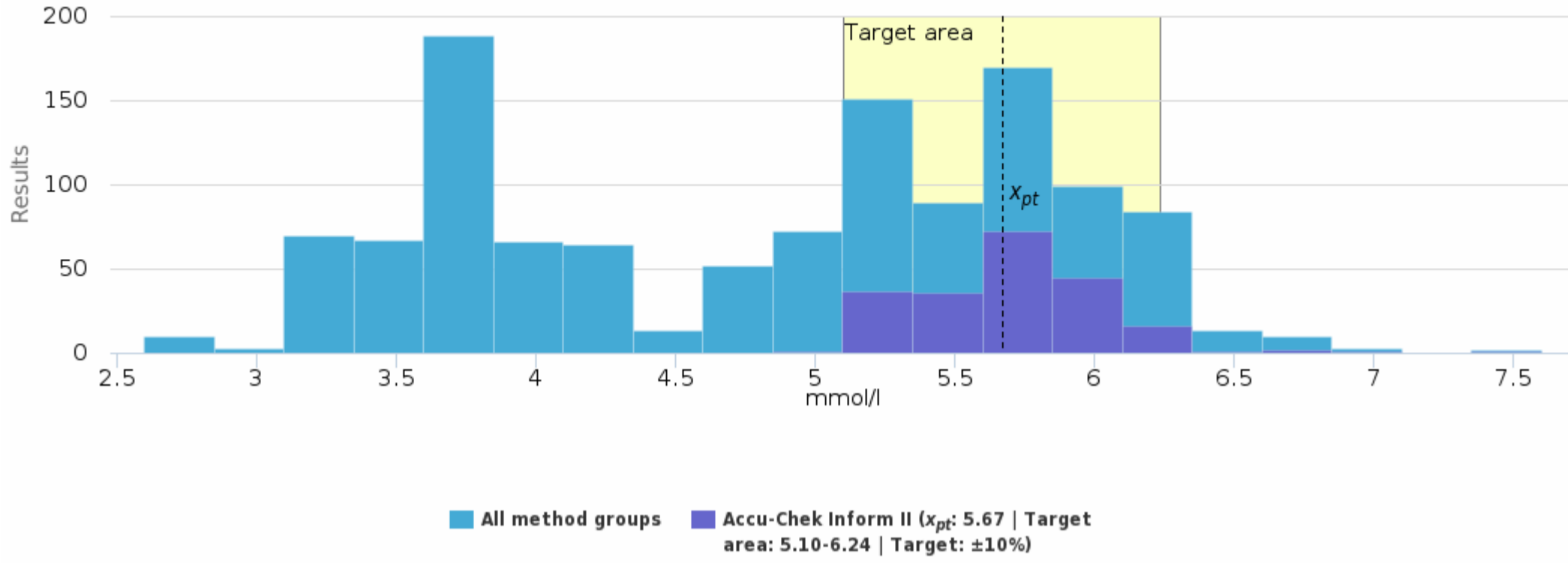
[info@labquality.fi](mailto:info@labquality.fi)

[www.labquality.com](http://www.labquality.com)

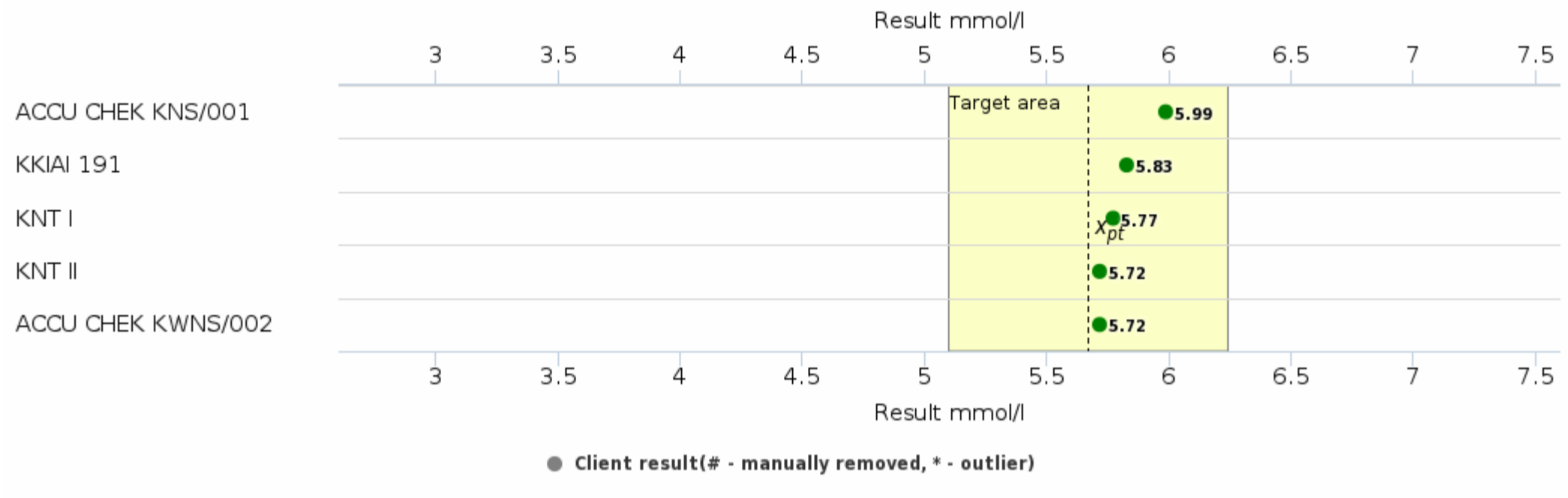


Sample S001|Glucose |Accu-Chek Inform II

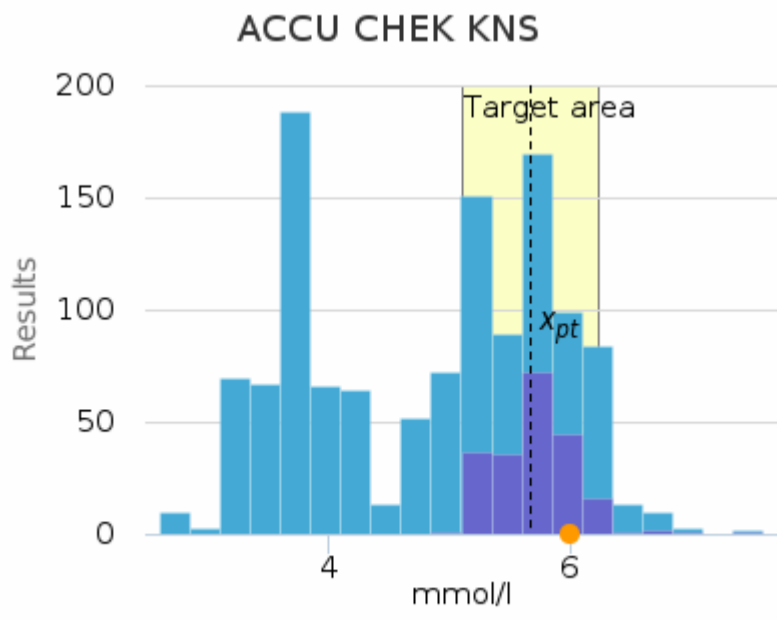
Sample S001-Glucose



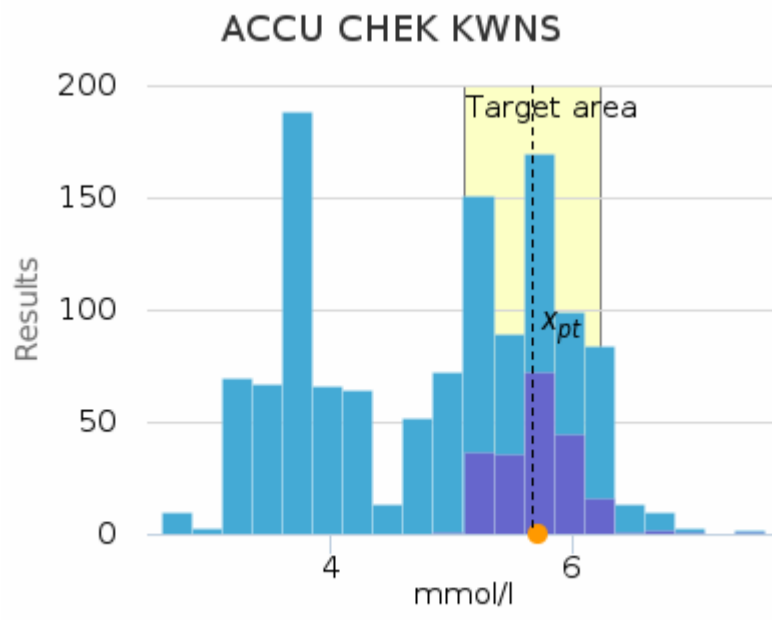
Results



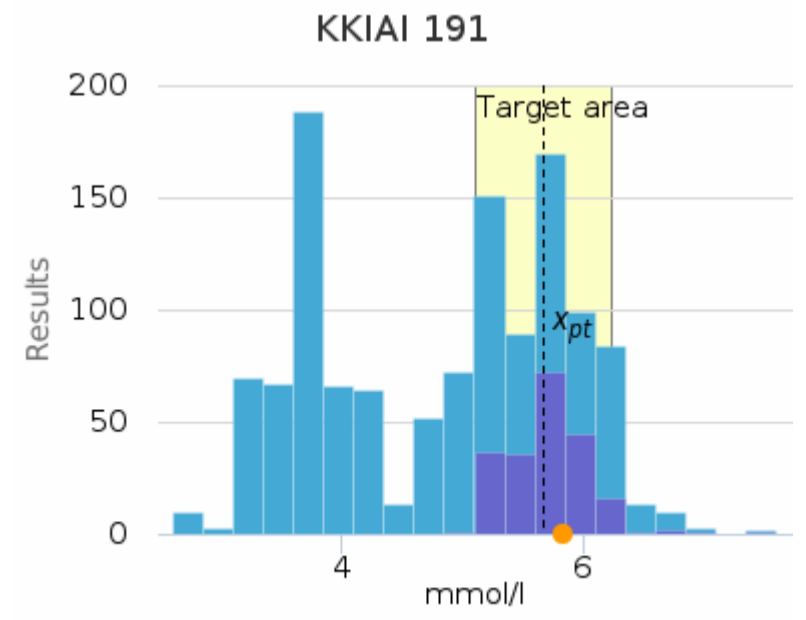
Sample S001|Glucose |Device specific histograms in LabScala



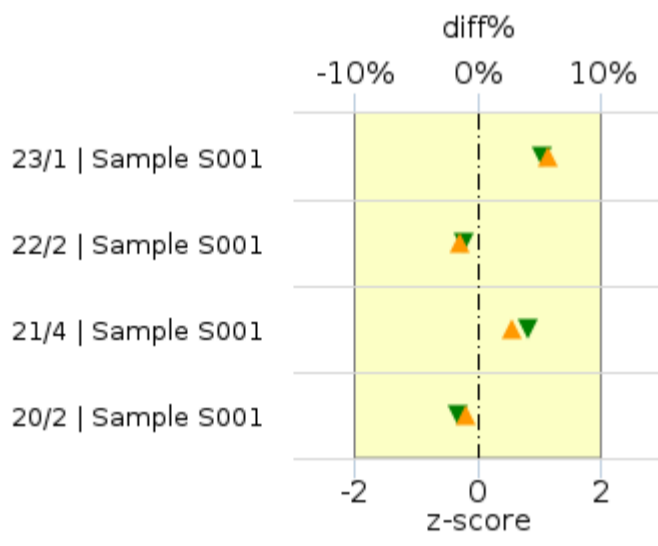
All method groups Accu-Chek Inform II  
 Own result: 5.99 (28.03.2023)  
 Diff%: 5.72 |  $x_{pt}$ : 5.67  
 Target area: 5.10-6.24 | Target:  $\pm 10\%$



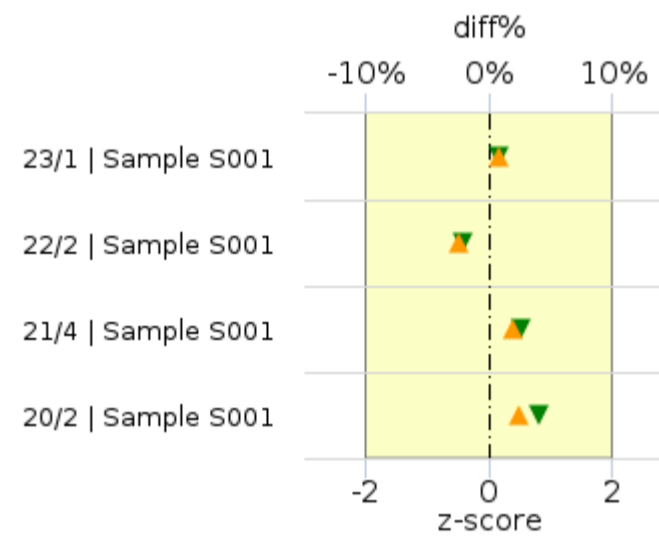
All method groups Accu-Chek Inform II  
 Own result: 5.72 (28.03.2023)  
 Diff%: 0.83 |  $x_{pt}$ : 5.67  
 Target area: 5.10-6.24 | Target:  $\pm 10\%$



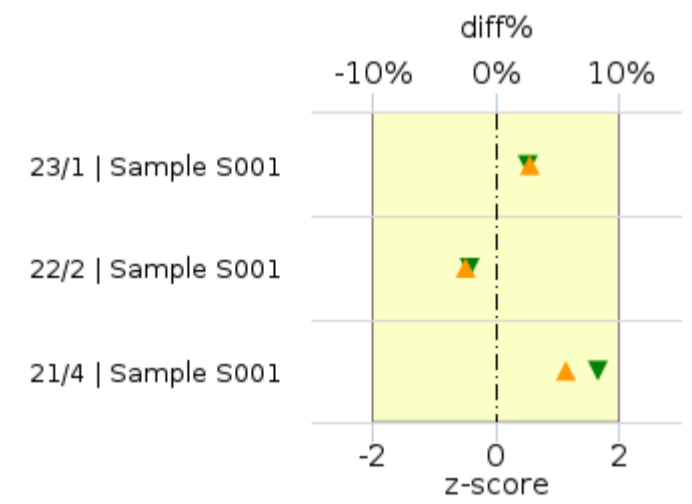
All method groups Accu-Chek Inform II  
 Own result: 5.83 (28.03.2023)  
 Diff%: 2.78 |  $x_{pt}$ : 5.67  
 Target area: 5.10-6.24 | Target:  $\pm 10\%$



▲ diff%  
 ▼ z-score



▲ diff%  
 ▼ z-score

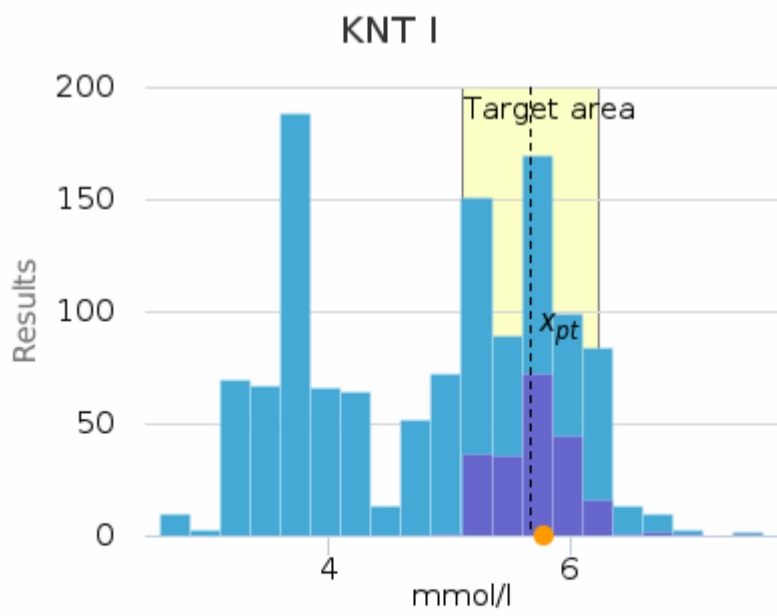


▲ diff%  
 ▼ z-score

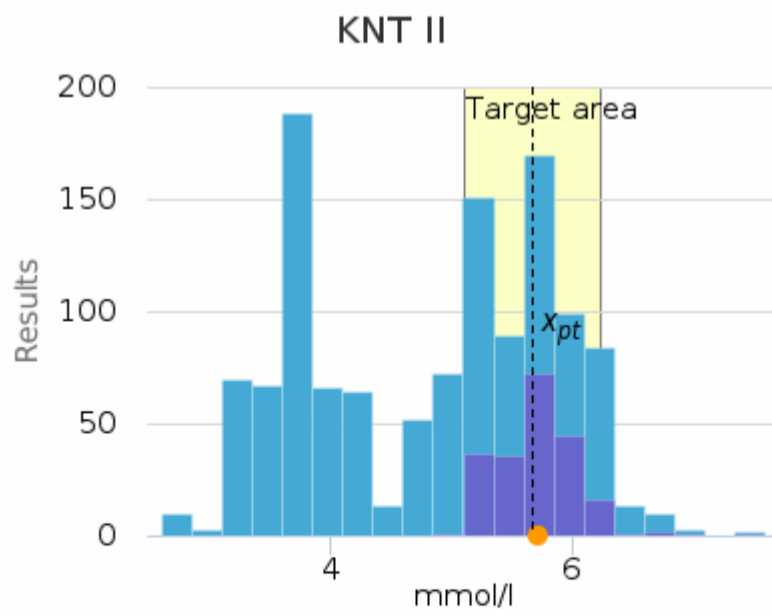
Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S001	5.67	5.99	5.72%	1.05
22/2	Sample S001	5.23	5.16	-1.38%	-0.24
21/4	Sample S001	5.78	5.94	2.81%	0.81
20/2	Sample S001	4.94	4.90	-0.93%	-0.31

Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S001	5.67	5.72	0.83%	0.15
22/2	Sample S001	5.23	5.11	-2.44%	-0.42
21/4	Sample S001	5.78	5.88	1.85%	0.53
20/2	Sample S001	4.94	5.06	2.41%	0.80

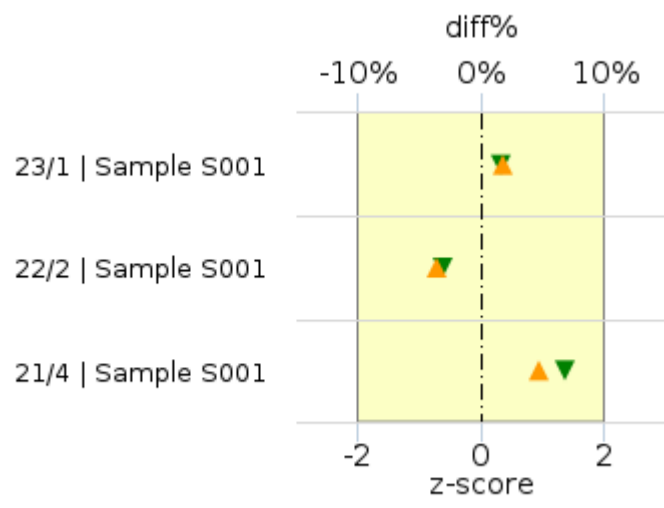
Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S001	5.67	5.83	2.78%	0.51
22/2	Sample S001	5.23	5.11	-2.44%	-0.42
21/4	Sample S001	5.78	6.11	5.69%	1.64



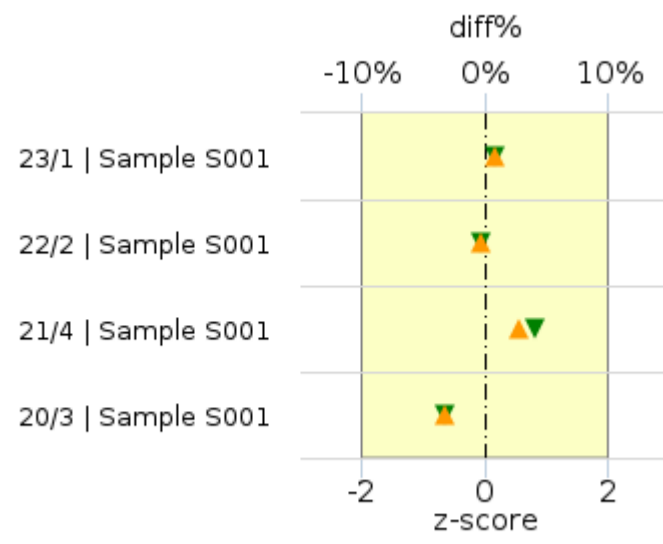
All method groups Accu-Chek Inform II  
 Own result: 5.77 (28.03.2023)  
 Diff%: 1.81 |  $x_{pt}$ : 5.67  
 Target area: 5.10-6.24 | Target:  $\pm 10\%$



All method groups Accu-Chek Inform II  
 Own result: 5.72 (28.03.2023)  
 Diff%: 0.83 |  $x_{pt}$ : 5.67  
 Target area: 5.10-6.24 | Target:  $\pm 10\%$



▲ diff%  
▼ z-score



▲ diff%  
▼ z-score

Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S001	5.67	5.77	1.81%	0.33
22/2	Sample S001	5.23	5.05	-3.50%	-0.61
21/4	Sample S001	5.78	6.05	4.73%	1.36

Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S001	5.67	5.72	0.83%	0.15
22/2	Sample S001	5.23	5.22	-0.32%	-0.06
21/4	Sample S001	5.78	5.94	2.81%	0.81
20/3	Sample S001	2.56	2.48	-3.28%	-0.65

**Report info****Participants**

404 participants from 10 countries.

**Report info**

Your own result should be compared to others using the same method.

Assigned values ( $\bar{x}_p$ , target values) are means of the results where results deviating more than  $\pm 3$  standard deviation from the median are removed. The standard uncertainty ( $u$ ) of

the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method.

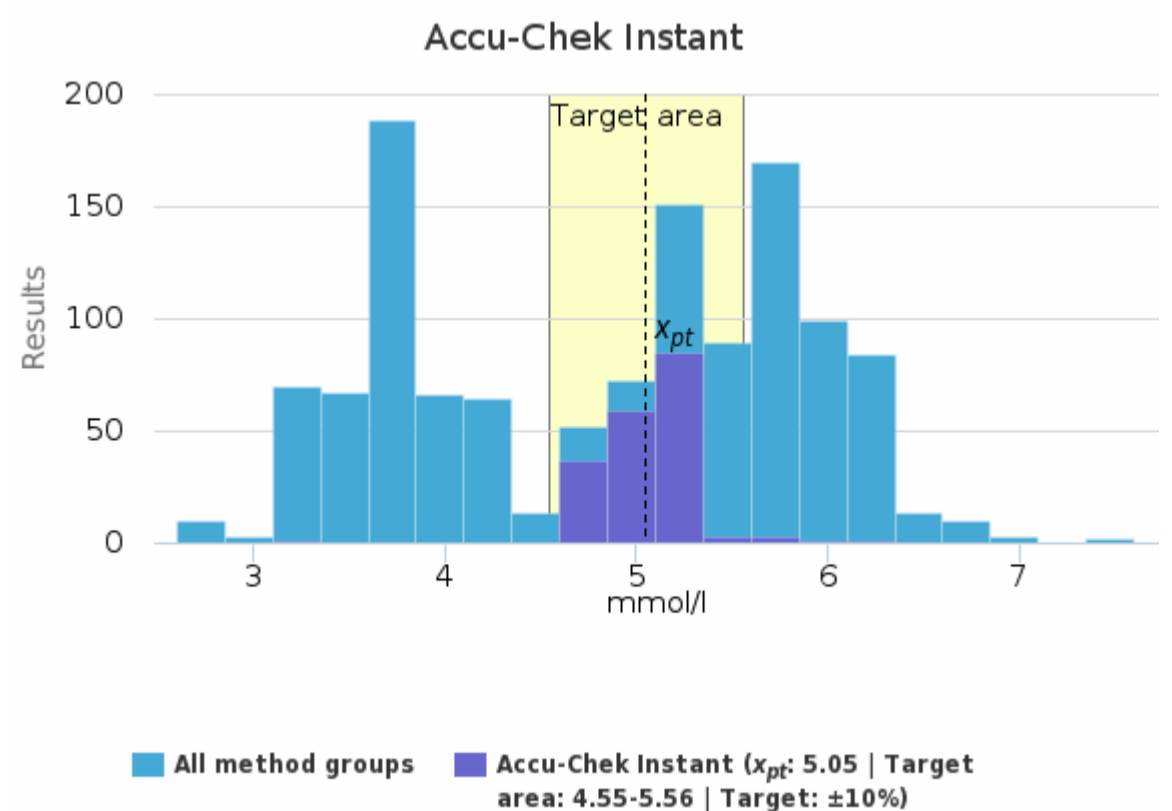
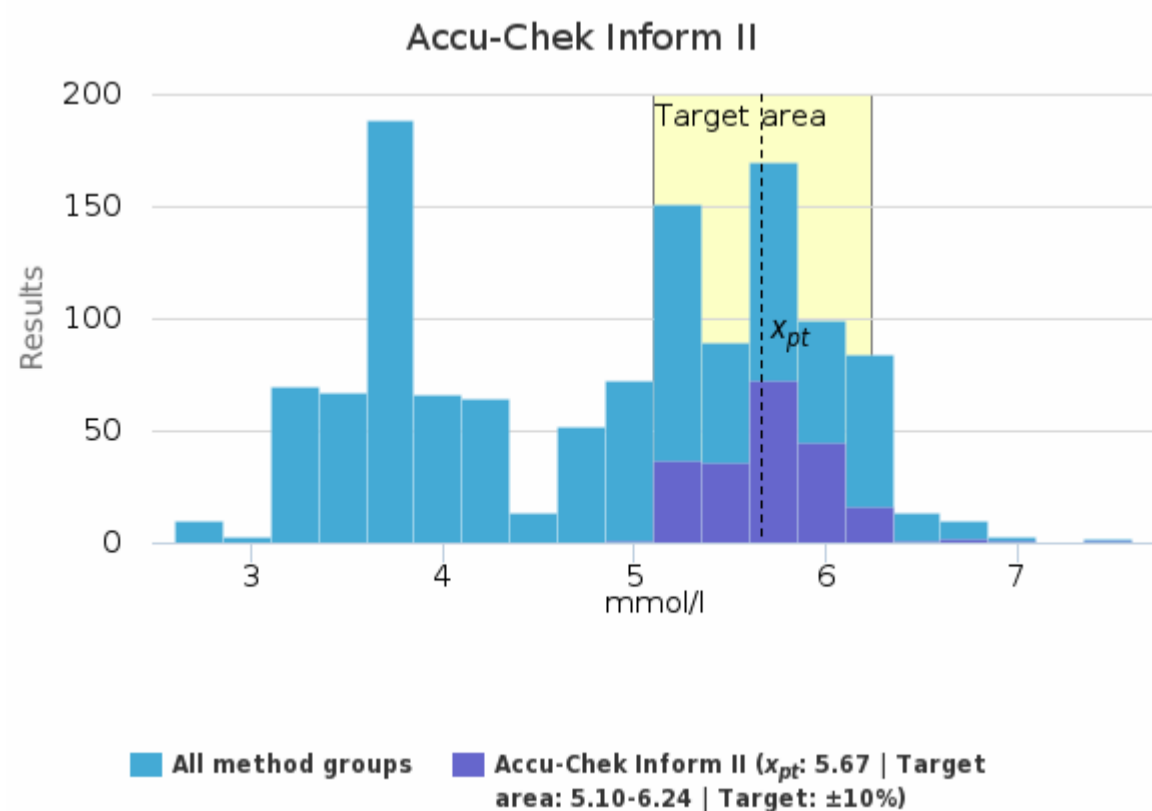
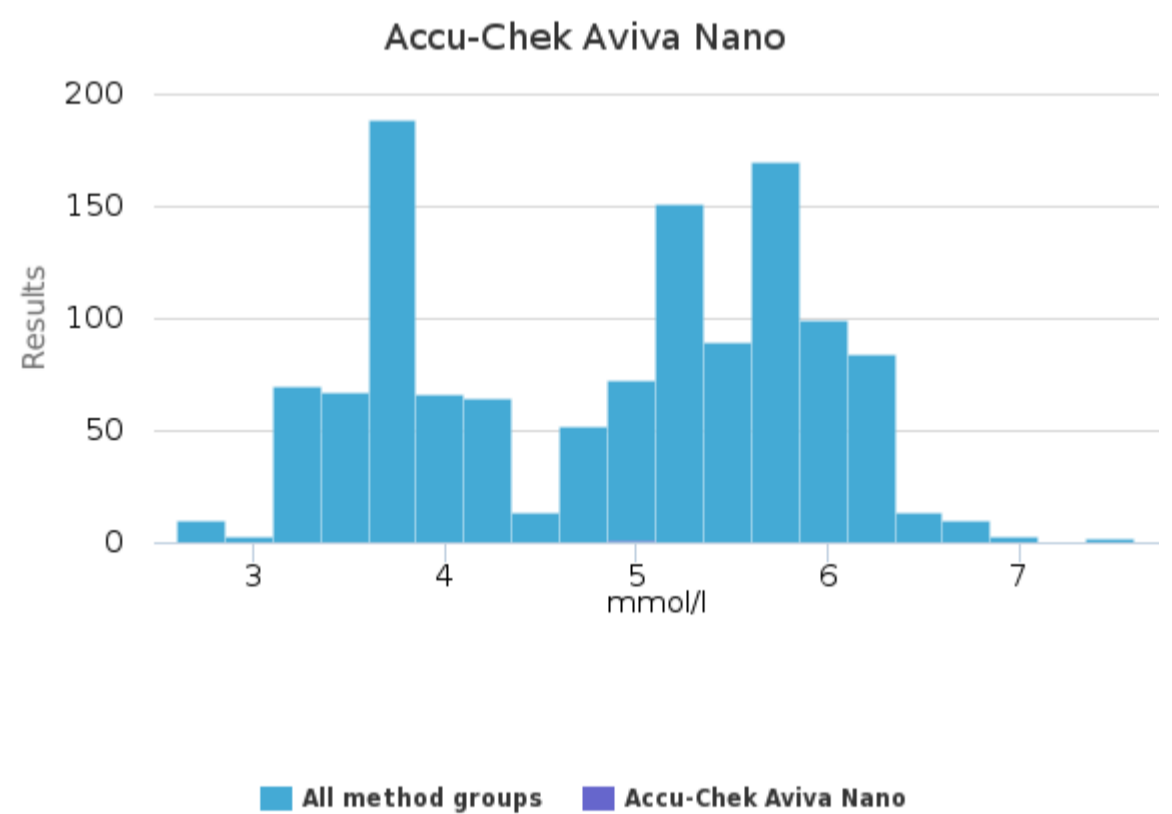
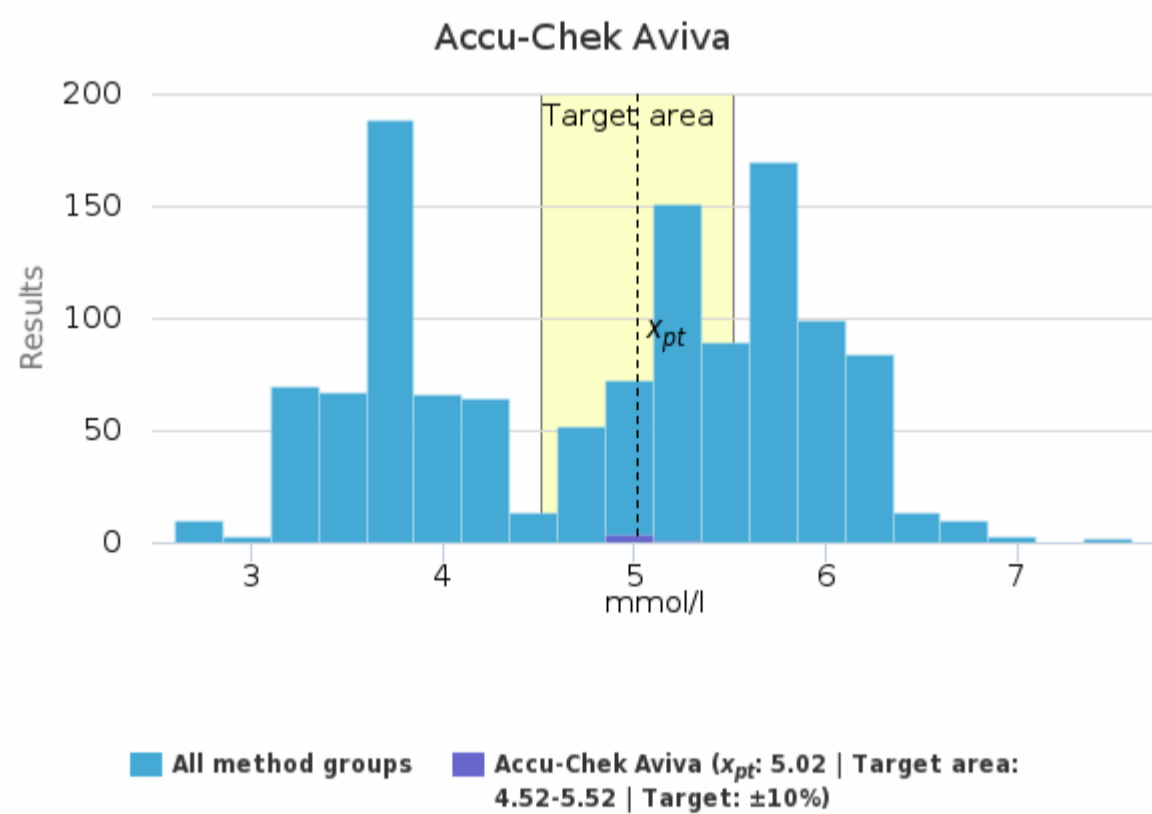
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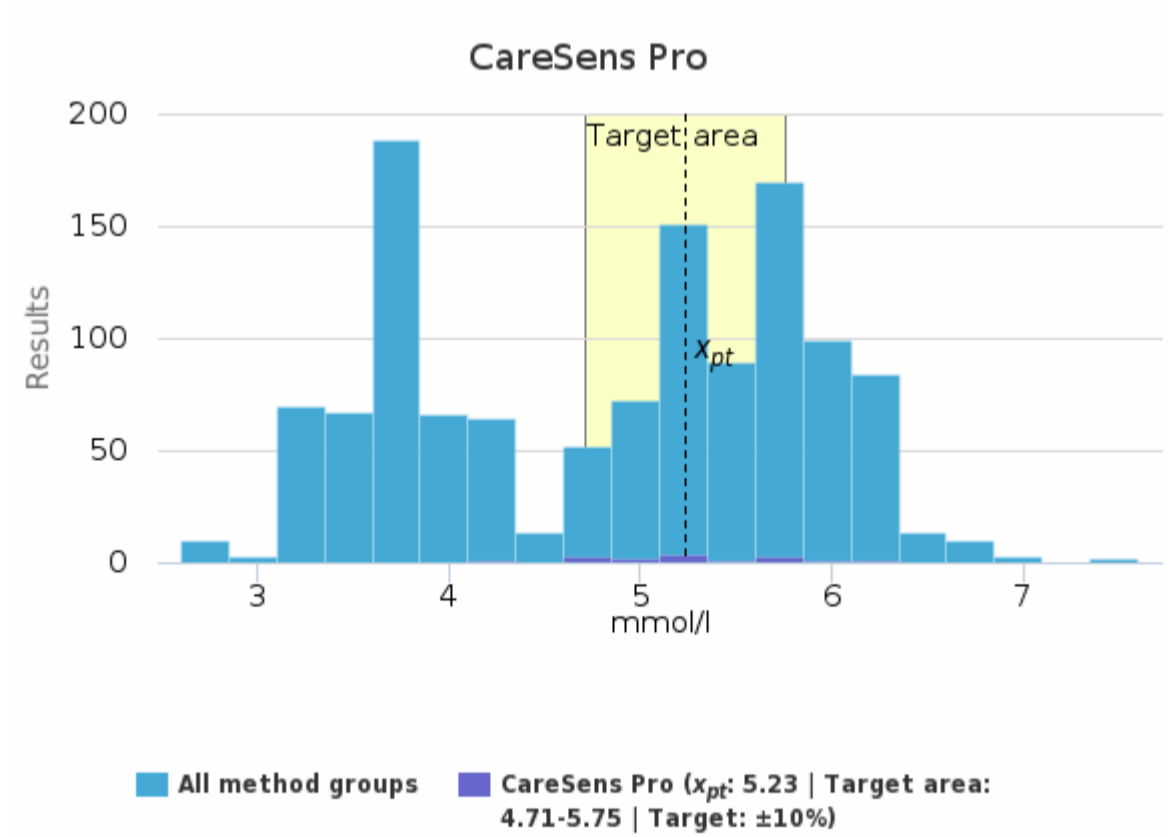
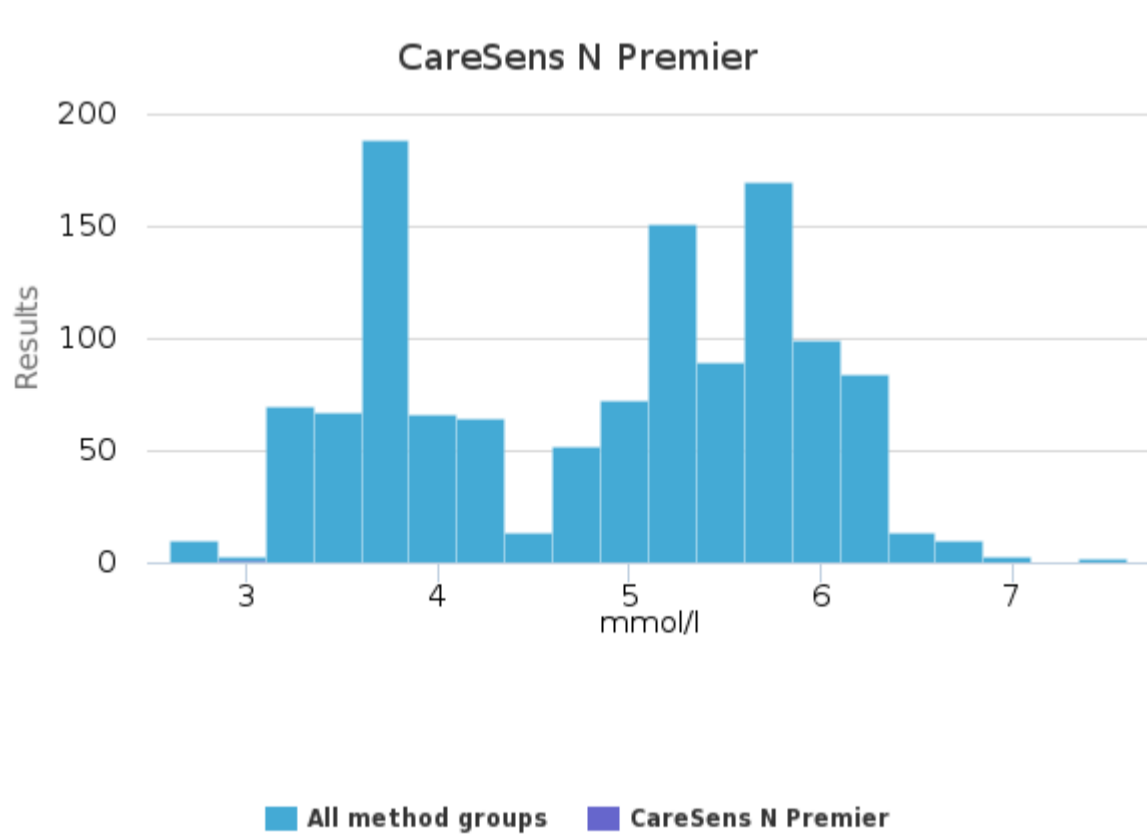
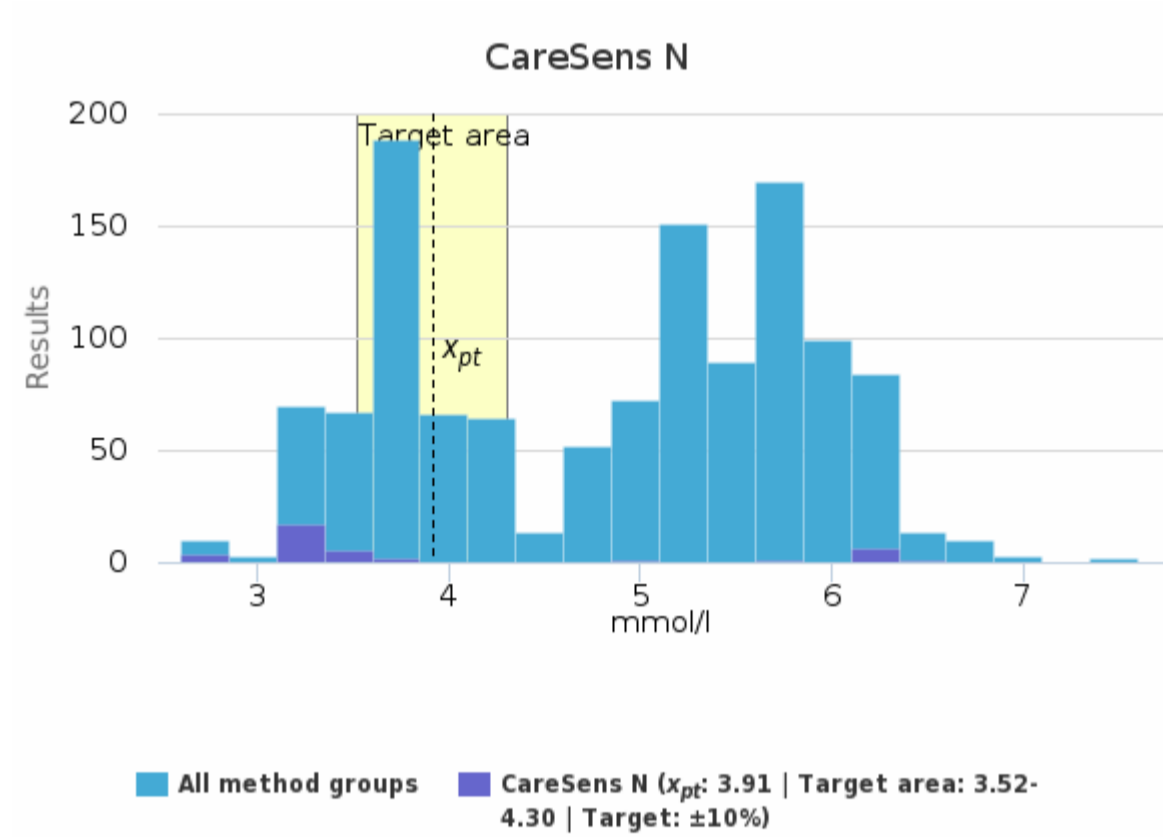
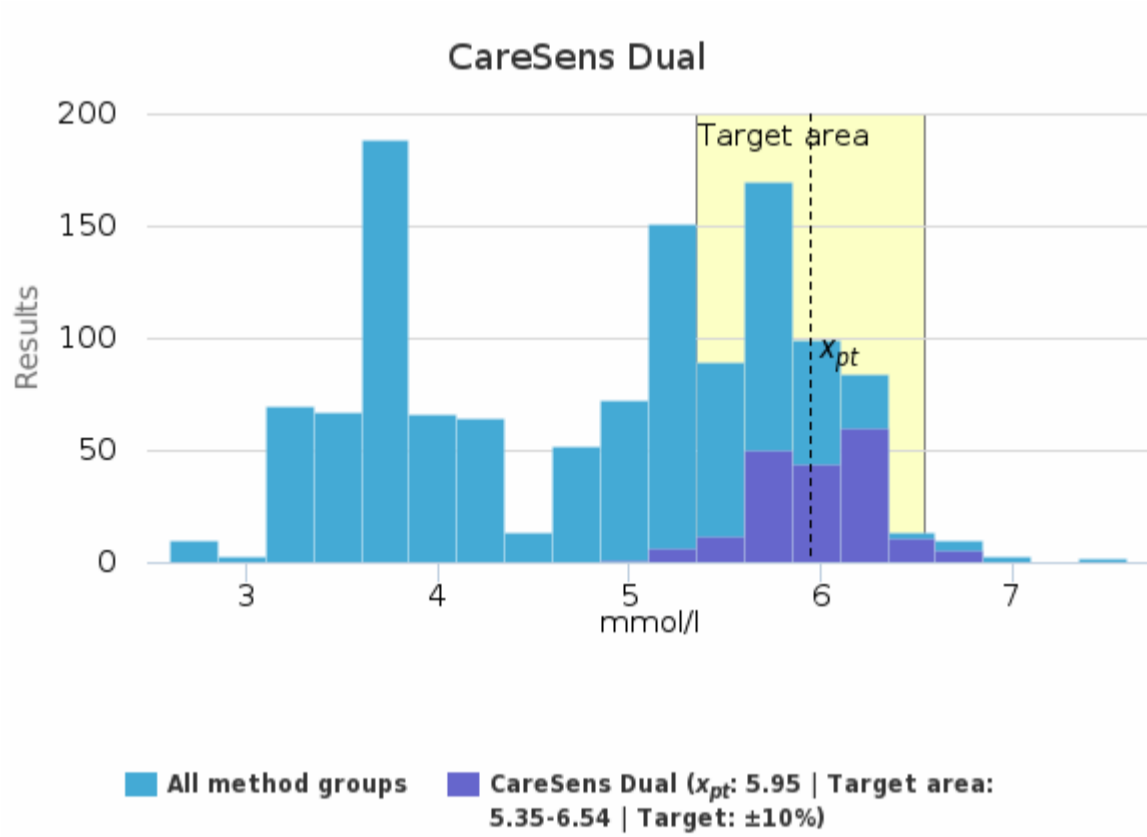
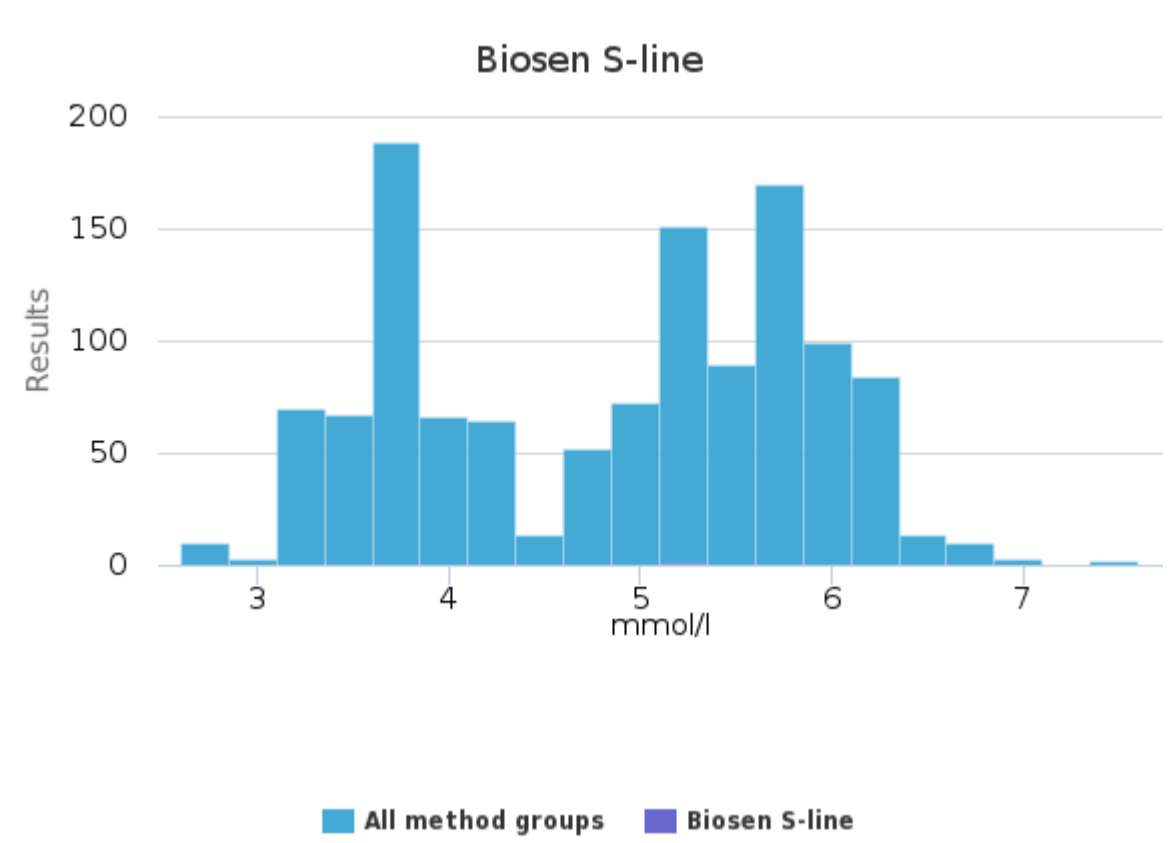
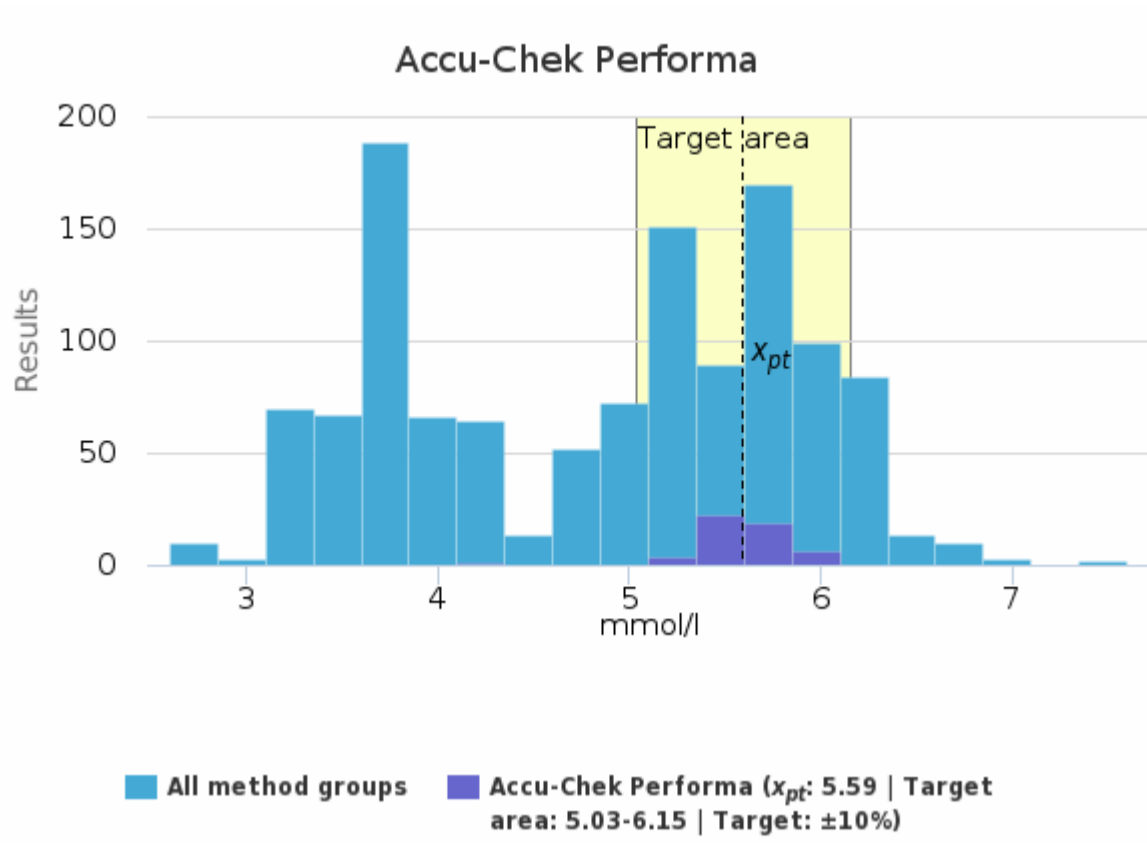
For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

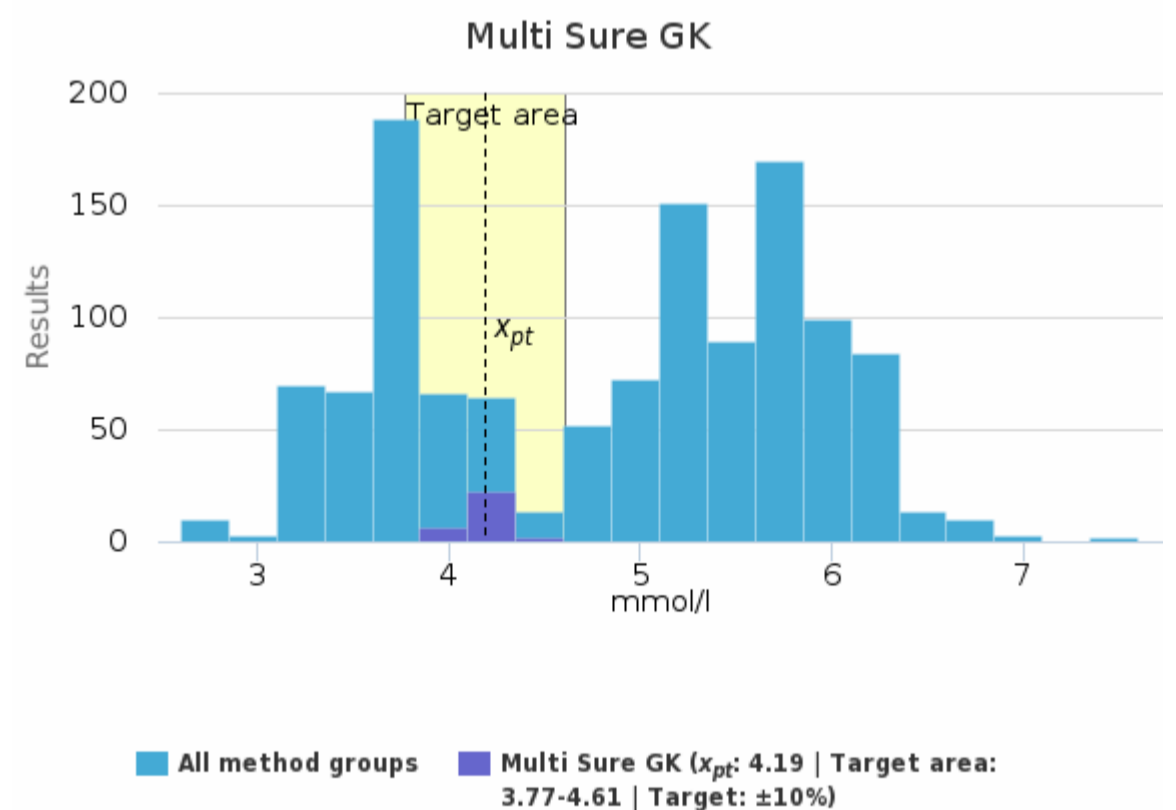
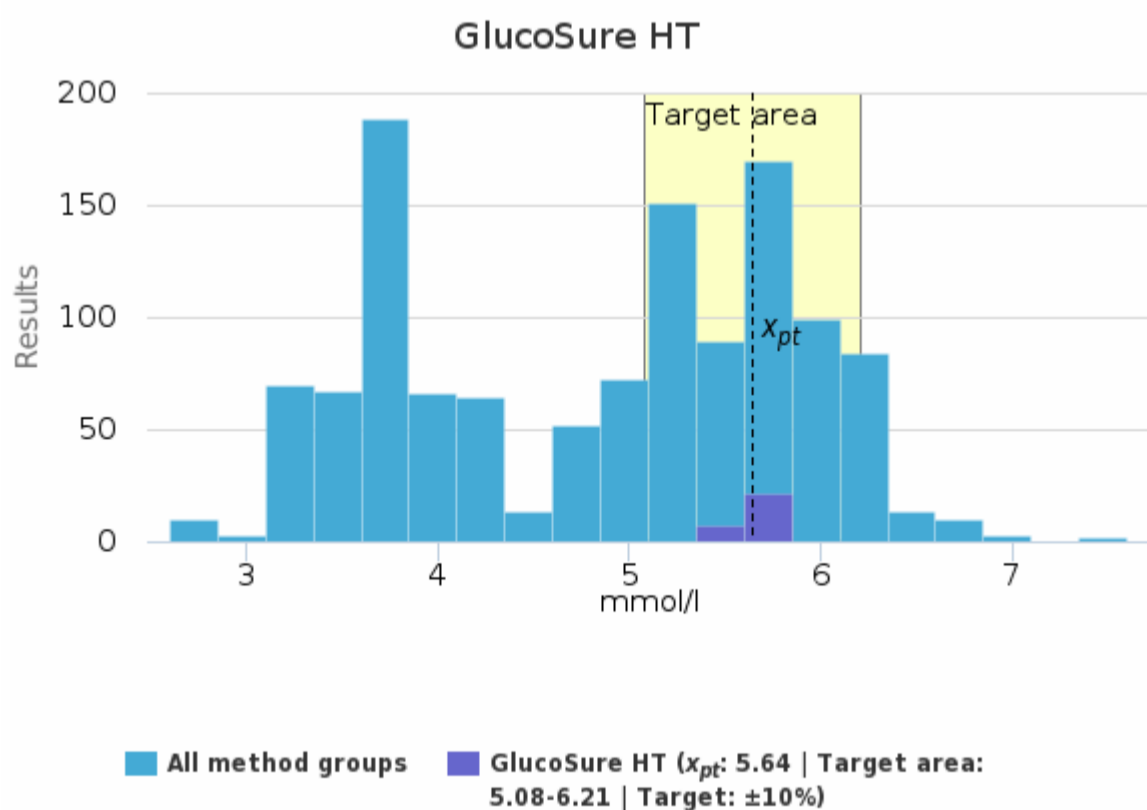
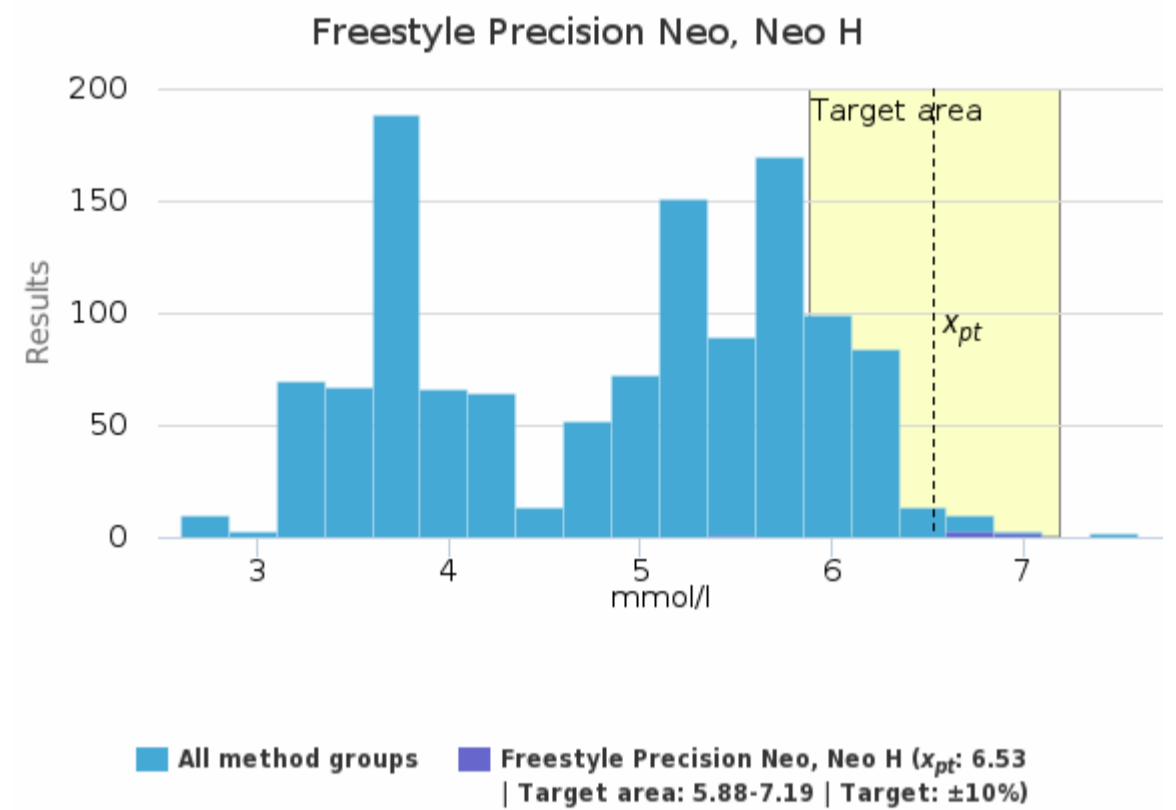
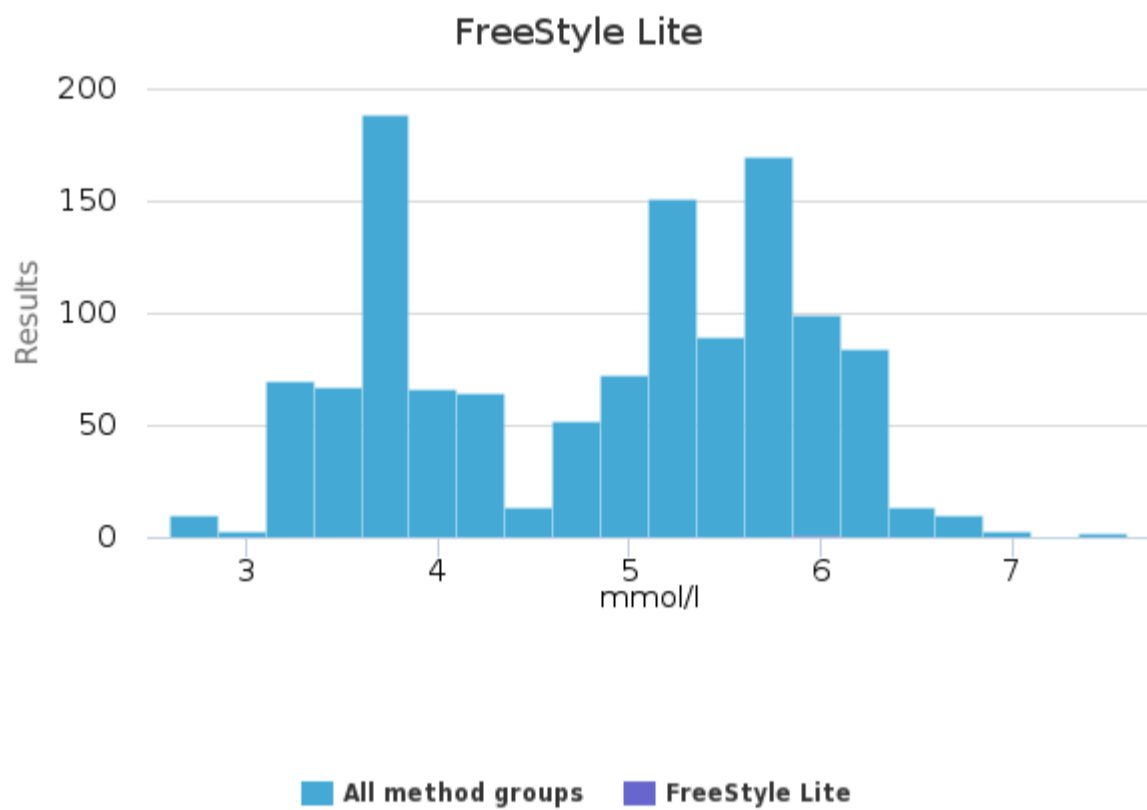
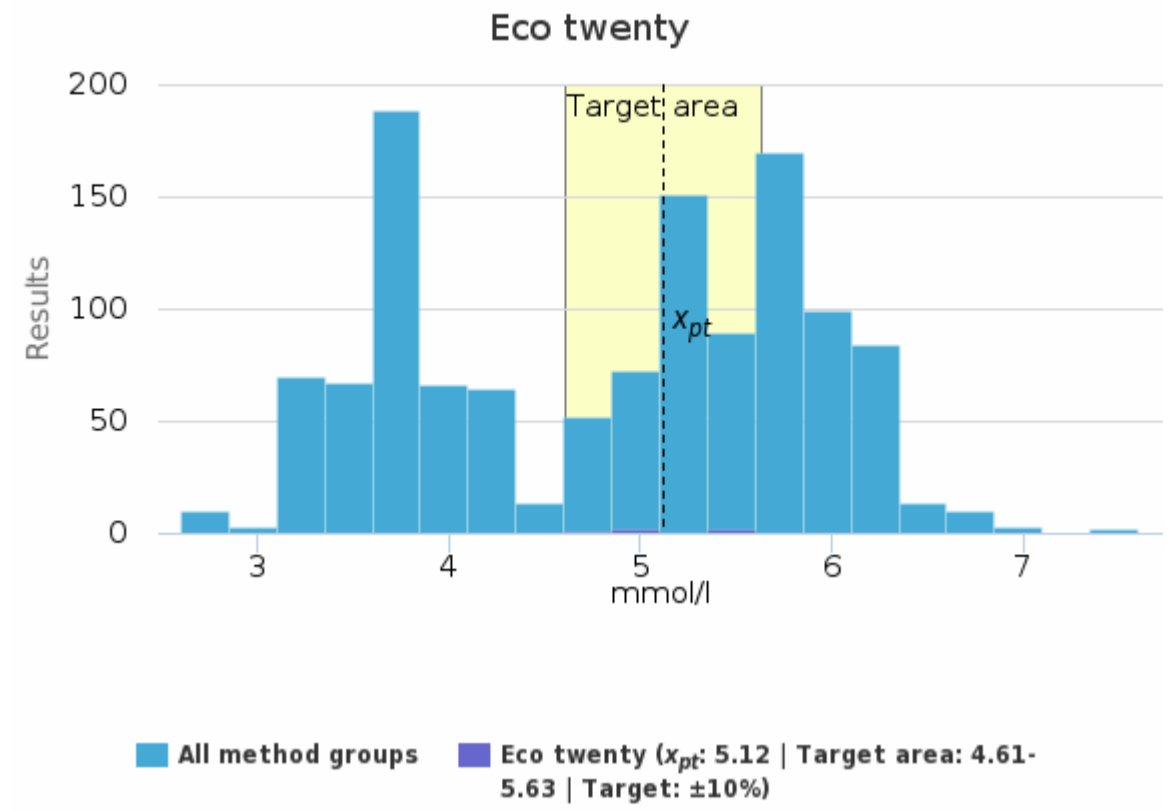
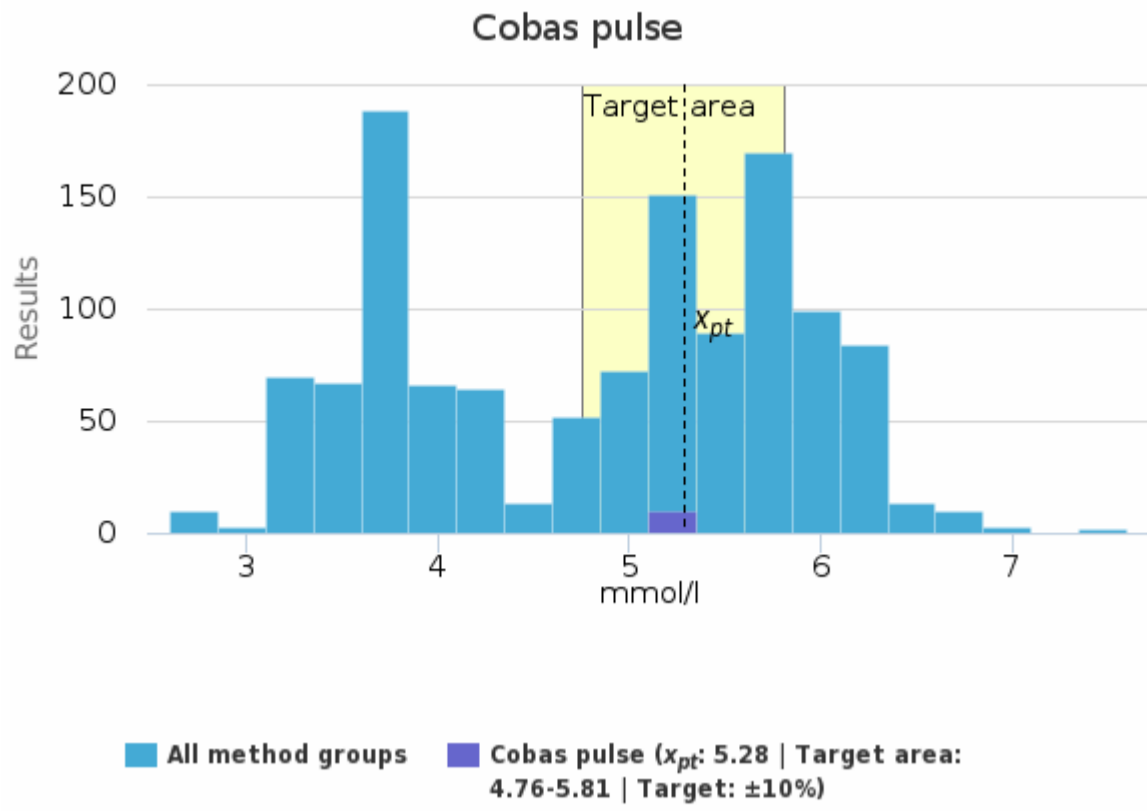
### Sample S001 | Glucose, mmol/l

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Accu-Chek Aviva	5.02	5.00	0.11	2.2	0.05	4.90	5.20	-	5
Accu-Chek Aviva Nano	-	-	-	-	-	5.00	5.00	-	1
Accu-Chek Inform II	5.67	5.70	0.31	5.4	0.02	4.90	6.72	3	212
Accu-Chek Instant	5.05	5.00	0.20	3.9	0.01	4.60	5.70	4	190
Accu-Chek Performa	5.59	5.50	0.20	3.6	0.03	5.20	6.00	1	52
Biosen S-line	-	-	-	-	-	5.31	5.31	-	1
CareSens Dual	5.95	5.90	0.31	5.2	0.02	5.20	6.70	1	189
CareSens N	3.91	3.30	1.27	32.5	0.21	2.70	6.40	-	37
CareSens N Premier	-	-	-	-	-	2.90	2.90	-	1
CareSens Pro	5.23	5.20	0.49	9.4	0.12	4.30	6.20	-	16
Cobas pulse	5.28	5.30	0.05	1.0	0.02	5.22	5.33	-	10
Eco twenty	5.12	5.09	0.35	6.9	0.16	4.71	5.58	-	5
FreeStyle Lite	-	-	-	-	-	5.90	5.90	-	1
Freestyle Precision Neo, Neo H	6.53	6.65	0.58	8.9	0.24	5.40	7.00	-	6
GlucoSure HT	5.64	5.66	0.10	1.8	0.02	5.44	5.77	-	28
Multi Sure GK	4.19	4.20	0.13	3.2	0.02	3.94	4.55	-	30
Mylife Pura	2.64	2.60	0.05	2.1	0.02	2.60	2.70	-	5
Mylife Unio	-	-	-	-	-	7.60	7.60	-	1
On Call Sure	3.70	3.70	0.30	8.2	0.01	2.90	4.60	4	417
Romed	-	-	-	-	-	2.60	2.60	-	1
StatStrip Glucose	5.32	5.40	0.34	6.3	0.10	4.60	5.90	-	12
Vivachek H+	4.69	4.72	0.13	2.9	0.06	4.44	4.83	-	6
<b>All</b>	<b>4.82</b>	<b>5.10</b>	<b>1.01</b>	<b>21.0</b>	<b>0.03</b>	<b>2.60</b>	<b>7.60</b>	<b>-</b>	<b>1226</b>

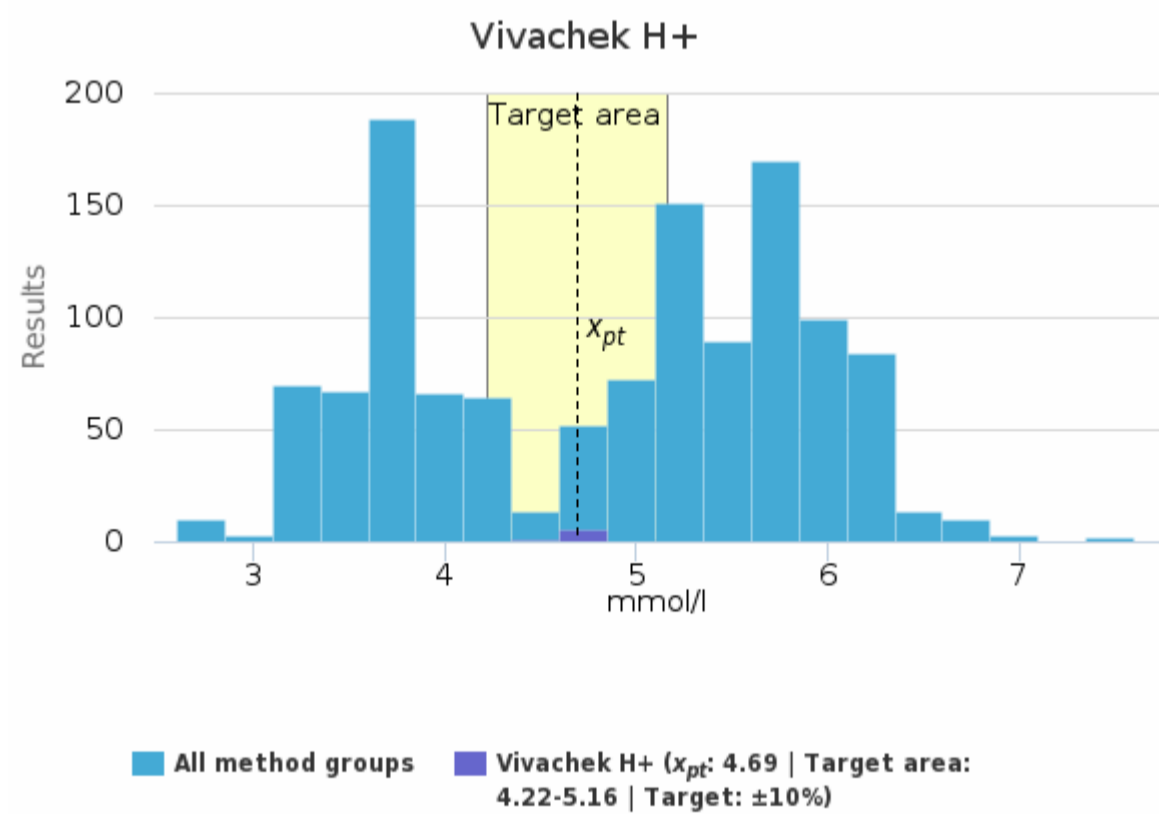
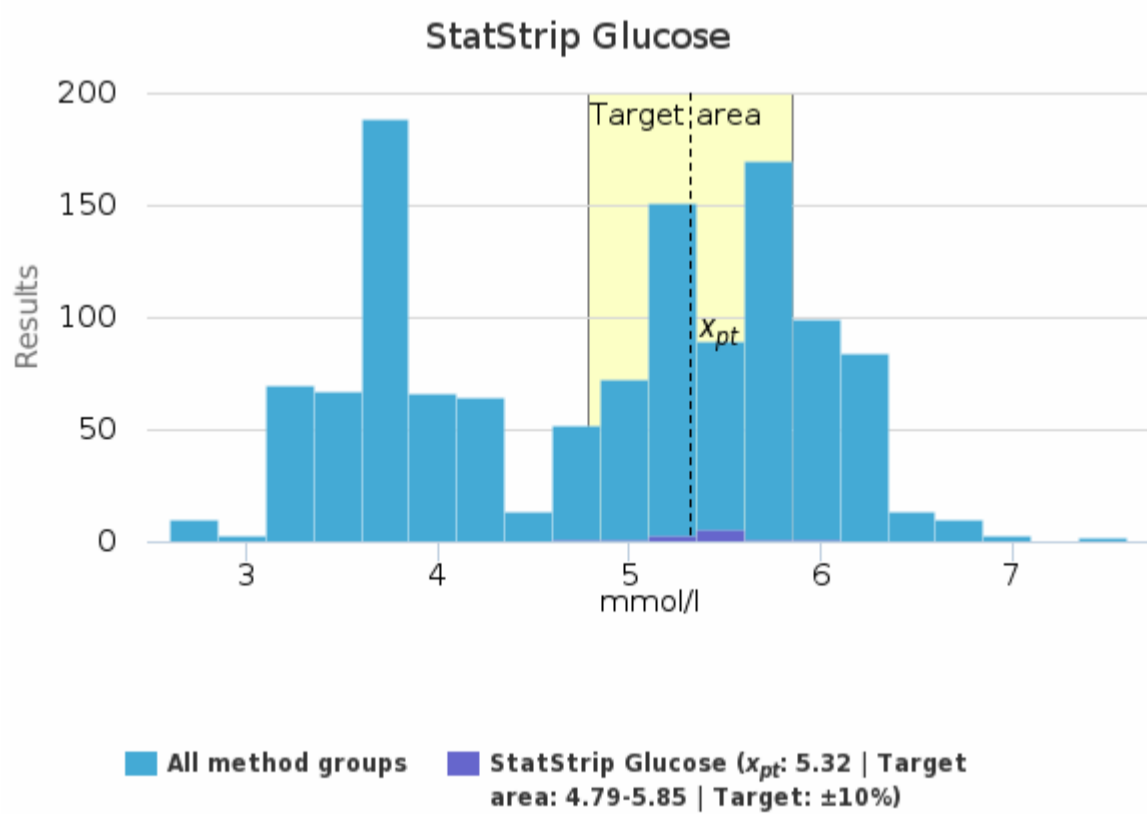
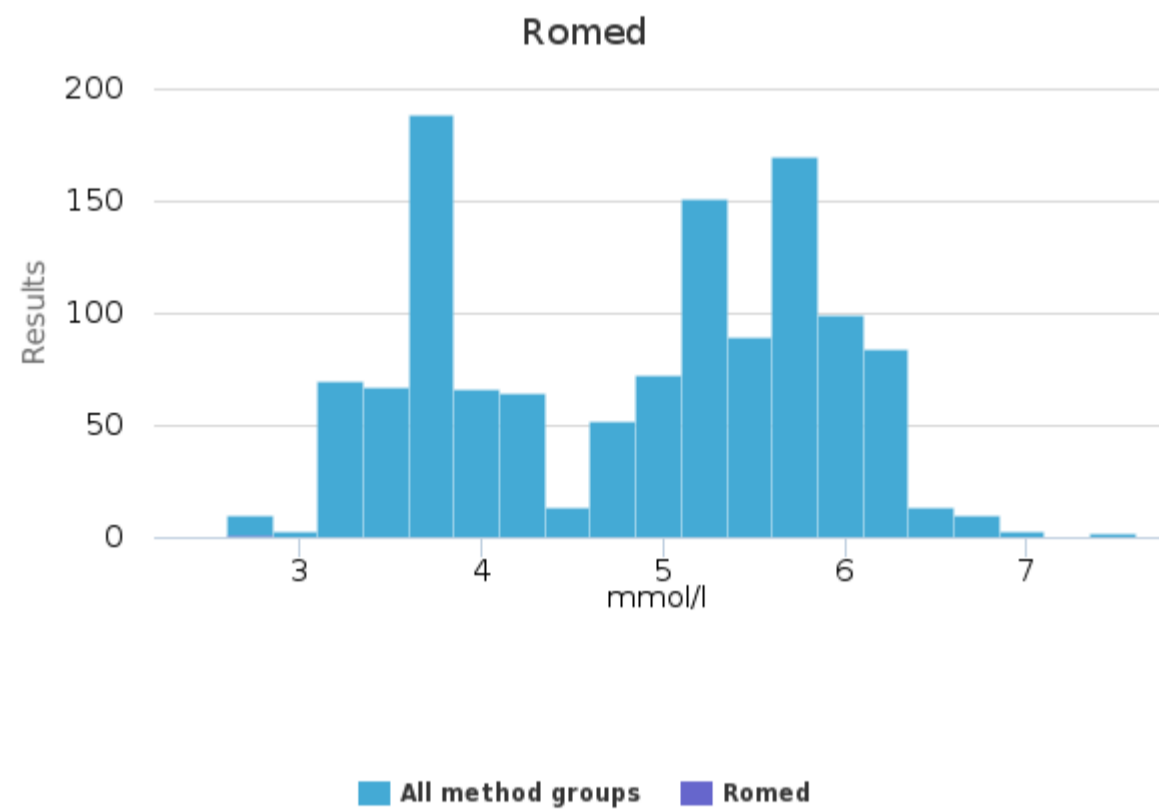
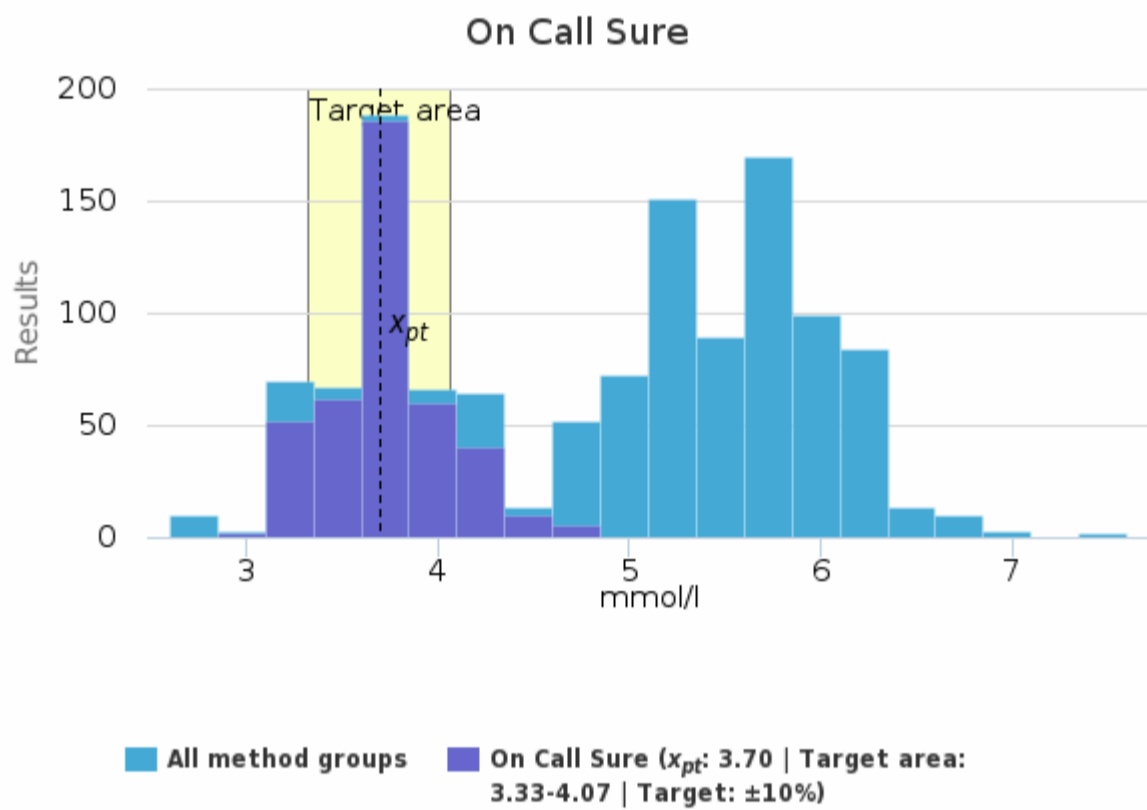
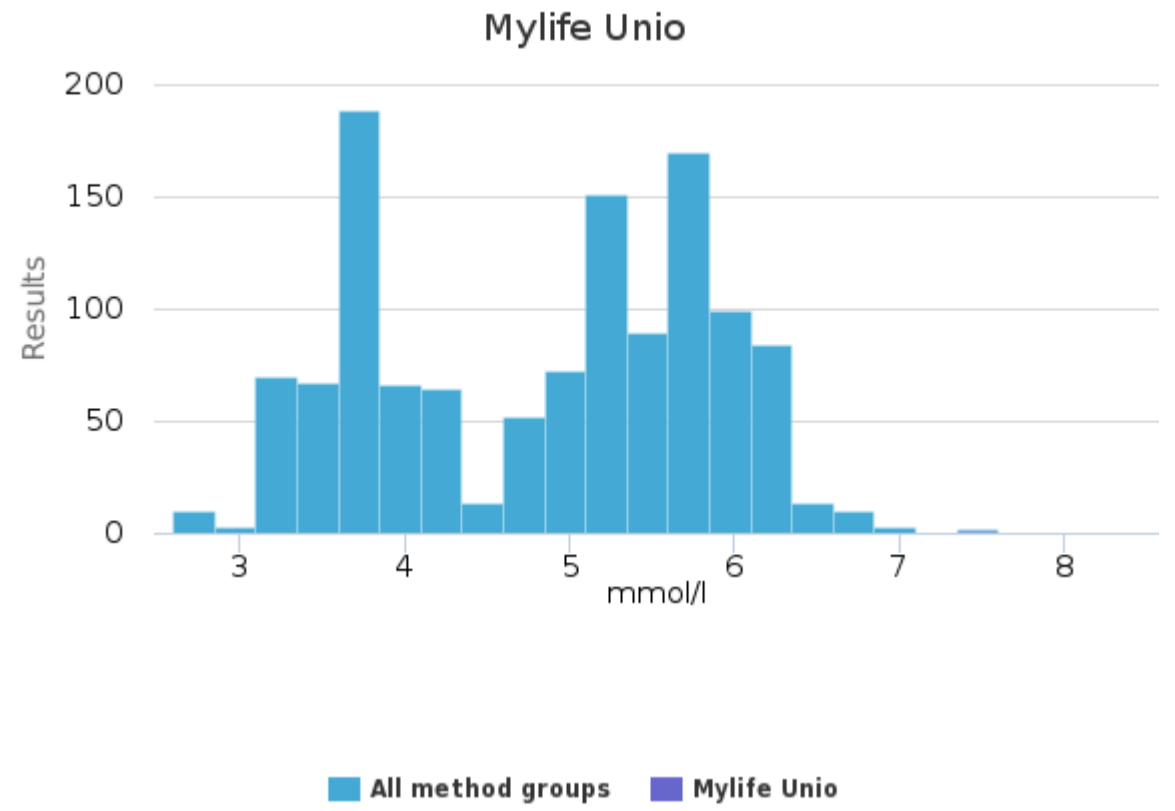
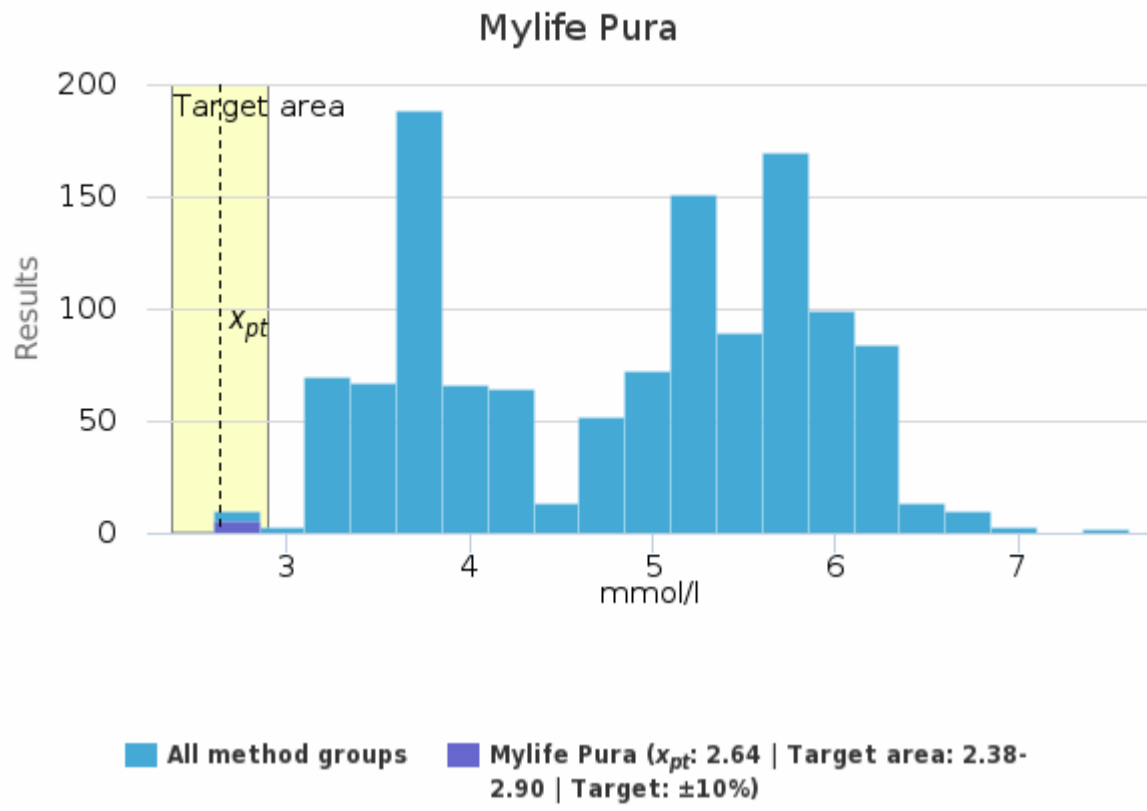
### Sample S001 | Glucose, mmol/l| histogram summaries in LabScala







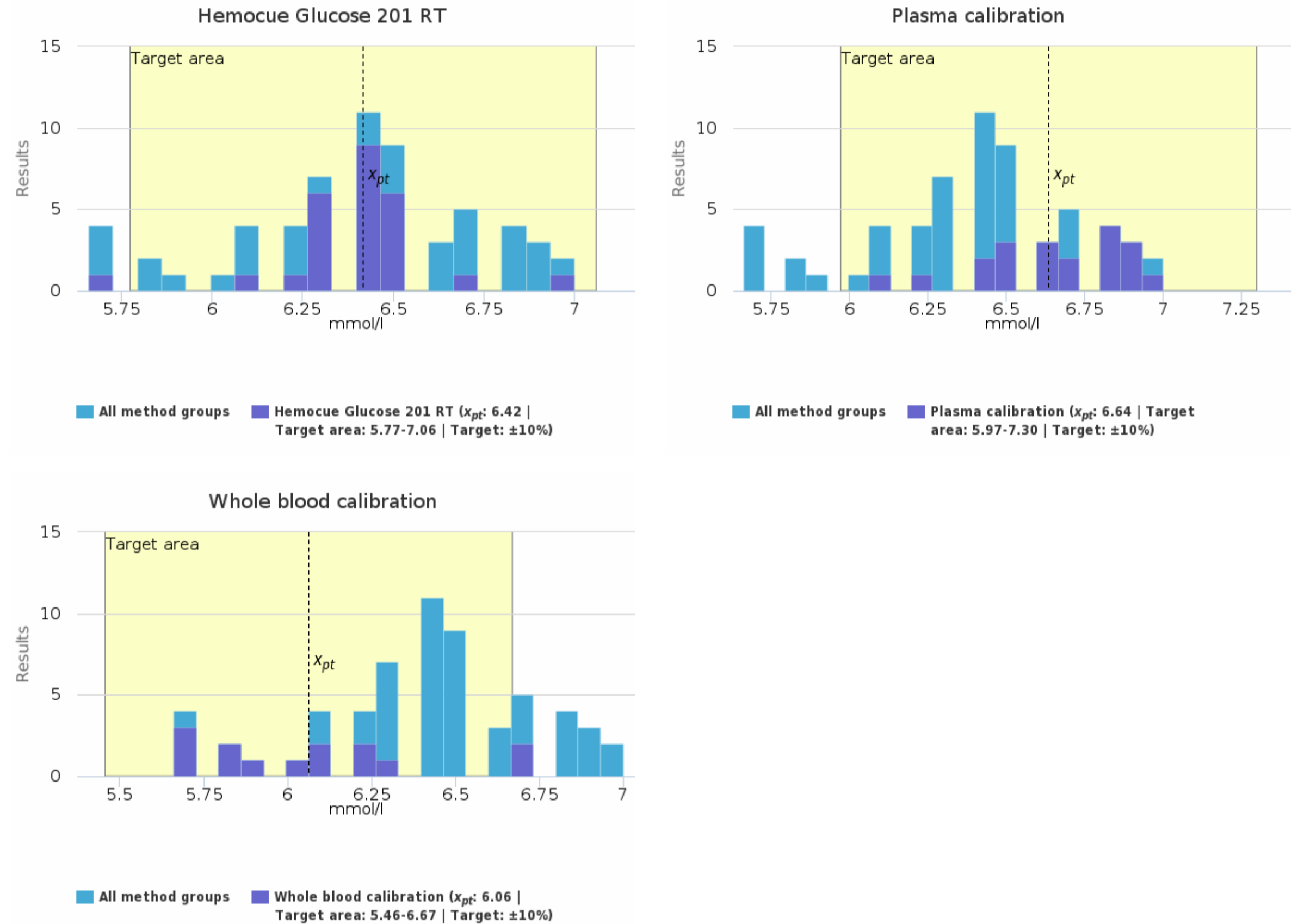




### Sample S002 | Glucose, mmol/l

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Hemocue Glucose 201 RT	6.42	6.40	0.17	2.6	0.03	6.10	7.00	1	26
Plasma calibration	6.64	6.65	0.24	3.6	0.05	6.10	7.00	-	20
Whole blood calibration	6.06	6.05	0.34	5.6	0.09	5.66	6.70	-	14
<b>All</b>	<b>6.39</b>	<b>6.40</b>	<b>0.33</b>	<b>5.2</b>	<b>0.04</b>	<b>5.66</b>	<b>7.00</b>	-	<b>60</b>

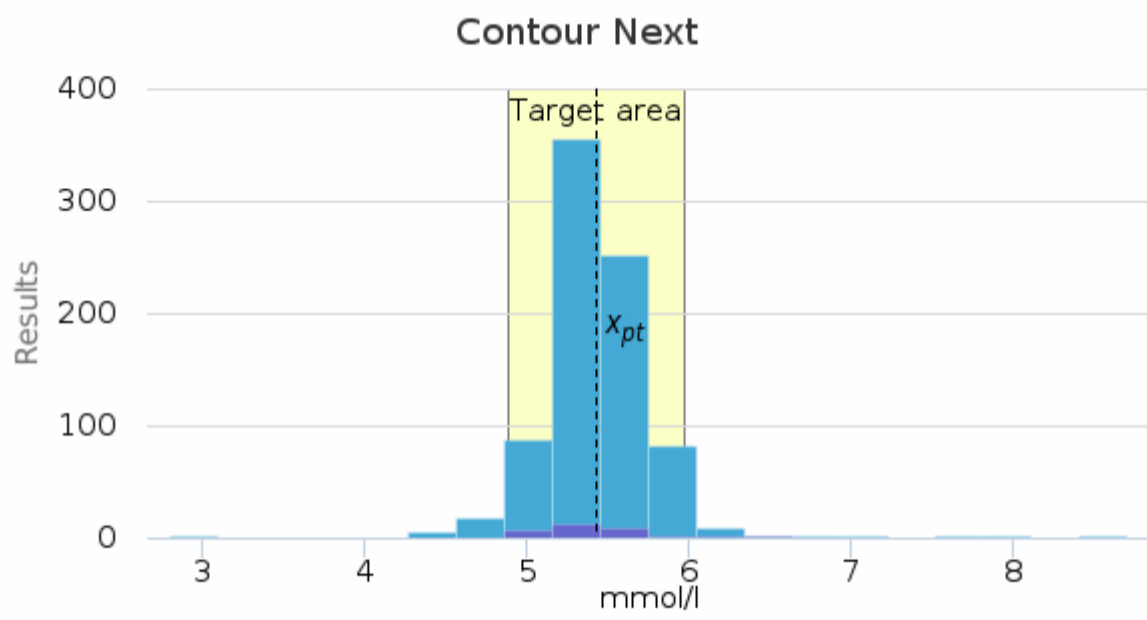
### Sample S002 | Glucose, mmol/l | histogram summaries in LabScala



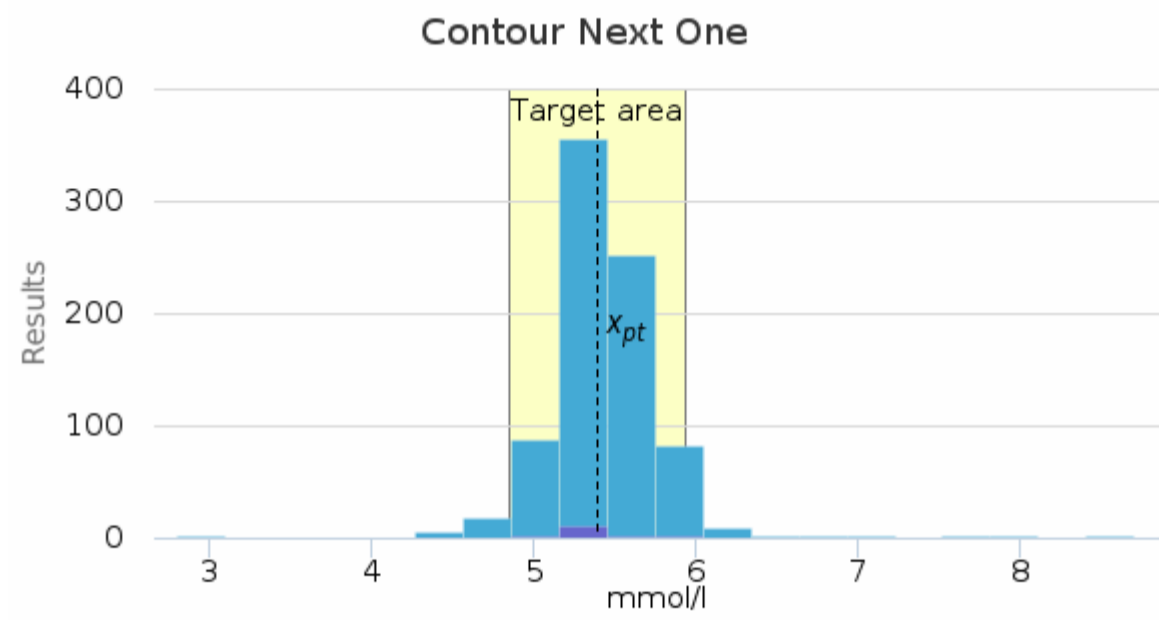
### Sample S003 | Glucose, mmol/l

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Contour Next	5.43	5.40	0.30	5.6	0.05	5.00	6.30	1	33
Contour Next One	5.39	5.30	0.22	4.1	0.06	5.10	5.90	-	15
Contour Plus /Contour Plus TestStrip	5.42	5.35	0.24	4.4	0.10	5.20	5.80	-	6
Contour XT/ Contour Next	5.42	5.40	0.28	5.1	0.01	4.40	6.30	7	761
<b>All</b>	<b>5.42</b>	<b>5.40</b>	<b>0.28</b>	<b>5.1</b>	<b>&lt;0.01</b>	<b>4.40</b>	<b>6.30</b>	<b>8</b>	<b>815</b>

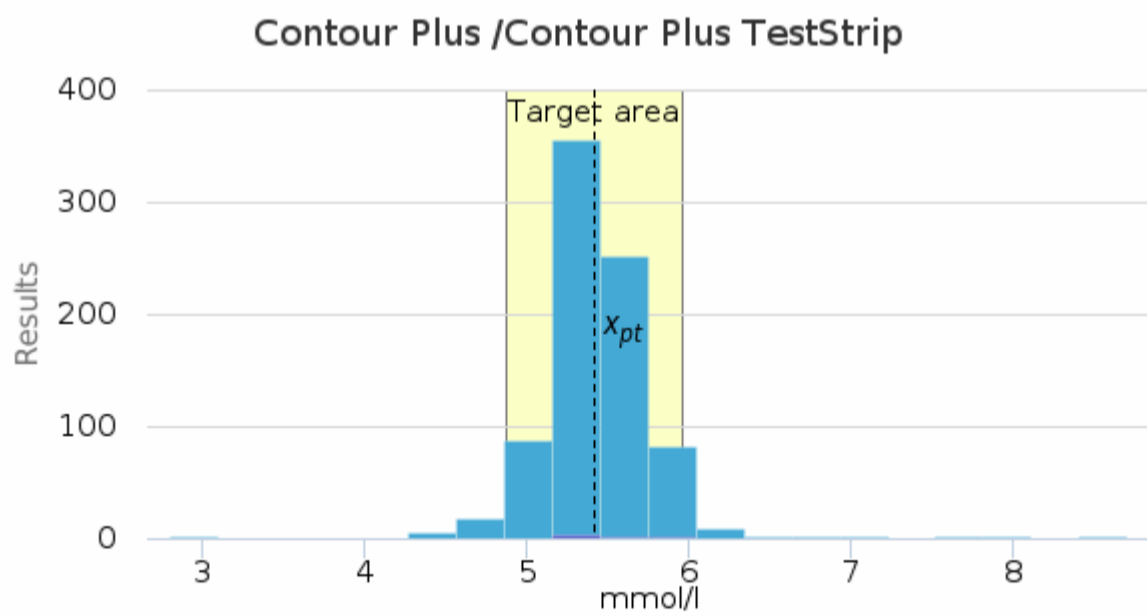
### Sample S003 | Glucose, mmol/l | histogram summaries in LabScala



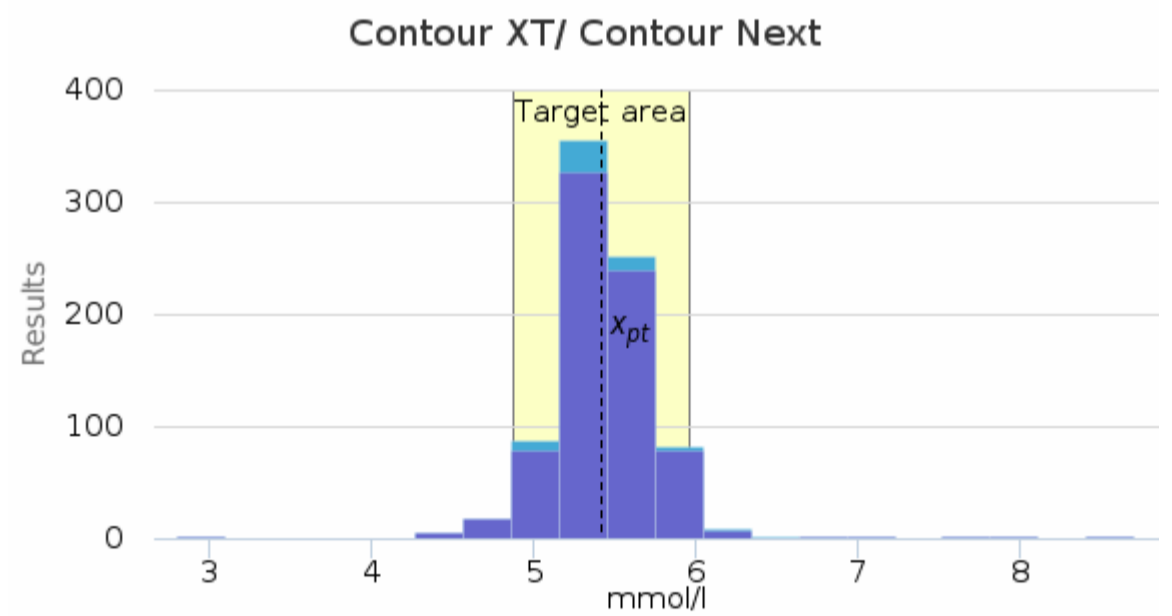
■ All method groups ■ Contour Next ( $x_{pt}$ : 5.43 | Target area: 4.89-5.98 | Target:  $\pm 10\%$ )



■ All method groups ■ Contour Next One ( $x_{pt}$ : 5.39 | Target area: 4.85-5.93 | Target:  $\pm 10\%$ )



■ All method groups ■ Contour Plus /Contour Plus TestStrip ( $x_{pt}$ : 5.42 | Target area: 4.88-5.96 | Target:  $\pm 10\%$ )



■ All method groups ■ Contour XT/ Contour Next ( $x_{pt}$ : 5.42 | Target area: 4.88-5.96 | Target:  $\pm 10\%$ )

**Report info****Participants**

404 participants from 10 countries.

**Report info**

Your own result should be compared to others using the same method.

Assigned values ( $\bar{x}_p$ , target values) are means of the results where results deviating more than  $\pm 3$  standard deviation from the median are removed. The standard uncertainty ( $u$ ) of

the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is large an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

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For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

External Quality Assessment Scheme

## Glucose meters, Round 1, 2023

### Specimens

Sample S001 (LQ729123011) and S003 (LQ729123013) were human-based whole blood products that contain additives and preservatives. Sample S002 (LQ729123012) was an animal-based hemolysate.

Based on the previous tests and the results of this round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

### Report info

Please see the description of the data analysis on the last page of the laboratory-specific histograms and Numerical Summary reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

As the samples contain additives and preservatives, the samples do not act like ordinary patient samples. Different method groups (different meters) are grouped together. Laboratories should compare their results primarily to the calculated assigned value of their method group i.e to the corrected method mean (marked as  $X_{pt}$  in the reports).

### Comments – Expert

The sample S001 was used for 22 different meter-/strip types. CV% was counted for 16 of those ( $n>1$ ). Only one (CareSense N) of those did not reach CV% <10 and was 32.5.

Sample S002 was used for Hemocue-meters, of which all reached CV% <10.

Sample S003 was used for four different Contour- meter-/strip types. Also all of those reached CV% <10.

### Annex 1.

Instructions how to proceed if your result is out of the acceptable limits.

### End of report

2023-04-21

### FINAL REPORT

Product no. 2570, 2580, 2590

Samples sent	2023-03-16
Round closed	2023-04-12
Final report	2023-04-21

### Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

### Authorized by

EQA Coordinator  
Liisa Ylitespa  
liisa.ylitespa@labquality.fi

### Expert

Adjunct Professor Linnéa Linko,  
Ph.D., Clinical Chemist, Quality Assurance, University of Turku, Finland

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Fax + 358 9 8566 8280

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www.labquality.com



## Annex 1.

Result outside acceptable limits

- Please read the meter and strip manual.
- Check that the strips / reagents included in the device are correct and the device is in working order. Check your measurement technique.
- Check and replace strips / reagents that are outdated, wetted, or stored, for example, at the wrong temperature.
- The device's own or unit's internal controls should be used regularly as instructed by the meter manufacturer / laboratory.
- Contact the person in charge at the support laboratory or the device manufacturer.

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